105TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { 105–713

MAMMOGRAPHY QUALITY STANDARDS REAUTHORIZATION ACT OF 1998

SEPTEMBER 14, 1998.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BLILEY, from the Committee on Commerce, submitted the following

R E P O R T

[To accompany H.R. 4382]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (H.R. 4382) to amend the Public Health Service Act to revise and extend the program for mammography quality standards, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

AMENDMENT

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Mammography Quality Standards Reauthorization Act of 1998".

SEC. 2. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Section 354(r)(2) of the Public Health Service Act (42 U.S.C. 263b(r)(2)) is amended in each of subparagraphs (A) and (B) by striking "1997" and inserting "2002".

(b) TECHNICAL AMENDMENTS.—Section 354(r)(2) of the Public Health Service Act (42 U.S.C. 263b(r)(2)) is amended in subparagraph (A) by striking "subsection (q)" and inserting "subsection (p)", and in subparagraph (B) by striking "fiscal year" and inserting "fiscal years".

SEC. 3. APPLICATION OF CURRENT VERSION OF APPEAL REGULATIONS.

Section 354(d)(2)(B) of the Public Health Service Act (42 U.S.C. 263b(d)(2)(B)) is amended by striking "42 C.F.R. 498 and in effect on the date of the enactment of this section" and inserting "part 498 of title 42, Code of Federal Regulations".

SEC. 4. ACCREDITATION STANDARDS.

(a) IN GENERAL.—Section 354(e)(1)(B) of the Public Health Service Act (42 U.S.C. 263b(e)(1)(B)) is amended—

(1) in clause (i), by striking "practicing physicians" each place such term appears and inserting "review physicians"; and

(2) in clause (ii), by striking "financial relationship" and inserting "relationship".

(b) DEFINITION.—Section 354(a) of the Public Health Service Act (42 U.S.C. 263b(a)) is amended by adding at the end the following:

"(8) REVIEW PHYSICIAN.—The term 'review physician' means a physician as prescribed by the Secretary under subsection (f)(1)(D) who meets such additional requirements as may be established by an accreditation body under subsection (e) and approved by the Secretary to review clinical images under subsection (e)(1)(B)(i) on behalf of the accreditation body.".

SEC. 5. CLARIFICATION OF FACILITIES' RESPONSIBILITY TO RETAIN MAMMOGRAM RECORDS.

Section 354(f)(1)(G) of the Public Health Service Act (42 U.S.C. 263b(f)(1)(G)) is amended by striking clause (i) and inserting the following:

"(i) a facility that performs any mammogram—

"(I) except as provided in subclause (II), maintain the mammogram in the permanent medical records of the patient for a period of not less than 5 years, or not less than 10 years if no subsequent mammograms of such patient are performed at the facility, or longer if mandated by State law; and

"(II) upon the request of or on behalf of the patient, transfer the mammogram to a medical institution, to a physician of the patient, or to the patient directly; and".

SEC. 6. DIRECT REPORTS TO PATIENTS.

Section 354(f)(1)(G)(ii) of the Public Health Service Act (42 U.S.C. 263b(f)(1)(G)(ii)) is amended by striking subclause (IV) and inserting the following:

"(IV) whether or not such a physician is available or there is no such physician, a summary of the written report shall be sent directly to the patient in terms easily understood by a lay person; and".

SEC. 7. SCOPE OF INSPECTIONS.

Section 354(g)(1)(A) of the Public Health Service Act (42 U.S.C. 263b(g)(1)(A)) is amended in the first sentence—

(1) by striking "certified"; and

(2) by inserting "the certification requirements under subsection (b) and" after "compliance with".

SEC. 8. DEMONSTRATION PROGRAM REGARDING FREQUENCY OF INSPECTIONS.

Section 354(g) of the Public Health Service Act (42 U.S.C. 263b(g)) is amended—

(1) in paragraph (1)(E), by inserting ", subject to paragraph (6)" before the period; and

(2) by adding at the end the following paragraph:

"(6) DEMONSTRATION PROGRAM.—

"(A) IN GENERAL.—The Secretary may establish a demonstration program under which inspections under paragraph (1) of selected facilities are conducted less frequently by the Secretary (or as applicable, by State or local agencies acting on behalf of the Secretary) than the interval specified in subparagraph (E) of such paragraph.

"(B) REQUIREMENTS.—Any demonstration program under subparagraph (A) shall be carried out in accordance with the following:

"(i) The program may not be implemented before April 1, 2001. Preparations for the program may be carried out prior to such date.

"(ii) In carrying out the program, the Secretary may not select a facility for inclusion in the program unless the facility is substantially free of incidents of noncompliance with the standards under subsection (f). The Secretary may at any time provide that a facility will no longer be included in the program.

"(iii) The number of facilities selected for inclusion in the program shall be sufficient to provide a statistically significant sample, subject to compliance with clause (ii).

"(iv) Facilities that are selected for inclusion in the program shall be inspected at such intervals as the Secretary determines will reasonably ensure that the facilities are maintaining compliance with such standards.".

SEC. 9. CLARIFICATION OF AUTHORITY TO DELEGATE INSPECTION RESPONSIBILITY TO LOCAL GOVERNMENT AGENCIES.

Section 354 of the Public Health Service Act (42 U.S.C. 263b) is amended—

(1) in subsections (a)(4), (g)(1), (g)(3), and (g)(4), by inserting "or local" after "State" each place such term appears;

(2) in the heading of subsection (g)(3), by inserting "OR LOCAL" after "STATE"; and

(3) in subsection (i)(1)(D)—

(A) by inserting "or local" after "State" the first place such term appears; and

(B) by inserting "or local agency" after "State" the second place such term appears.

SEC. 10. PATIENT NOTIFICATION CONCERNING HEALTH RISKS.

(a) REQUIREMENT.—Section 354(h) of the Public Health Service Act (42 U.S.C. 263b(h)) is amended—

(1) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(2) by inserting after paragraph (1) the following:

"(2) PATIENT INFORMATION.—If the Secretary determines that the quality of mammography performed by a facility (whether or not certified pursuant to subsection (c)) was so inconsistent with the quality standards established pursuant to subsection (f) as to present a significant risk to individual or public health, the Secretary may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the Secretary may require.".

(b) CIVIL MONEY PENALTY.—Section 354(h)(3) of the Public Health Service Act (42 U.S.C. 263b(h)(3)), as redesignated by subsection (a)(1), is amended—

(1) by striking "and" at the end of subparagraph (B);

(2) by redesignating subparagraph (C) as subparagraph (D); and

(3) by inserting after subparagraph (B) the following:

"(C) each failure to notify a patient of risk as required by the Secretary pursuant to paragraph (2), and".

(c) CONFORMING AMENDMENT.—Section 354(h)(4) of the Public Health Service Act (42 U.S.C. 263b(h)(4)), as redesignated by subsection (a)(1), is amended by striking "paragraphs (1) and (2)" and inserting "paragraphs (1) through (3)".

SEC. 11. REQUIREMENT TO COMPLY WITH INFORMATION REQUESTS.

Section 354(i)(1)(C) of the Public Health Service Act (42 U.S.C. 263b(i)(1)(C)) is amended—

(1) by inserting after "Secretary" the first place such term appears the following: "(or of an accreditation body approved pursuant to subsection (e))"; and

(2) by inserting after "Secretary" the second place such term appears the following: "(or such accreditation body or State carrying out certification program requirements pursuant to subsection (q))".

SEC. 12. ADJUSTMENT TO SEVERITY OF SANCTIONS.

Section 354(i)(2)(A) of the Public Health Service Act (42 U.S.C. 263b(i)(2)(A)) is amended by striking "makes the finding" and all that follows and inserting the following: "has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that—

"(i) the failure or violation was intentional; or

"(ii) the failure or violation presents a serious risk to human health.".

SEC. 13. TECHNICAL AMENDMENT.

Section 354(q)(4)(B) of the Public Health Service Act (42 U.S.C. 263b(q)(4)(B)) is amended by striking "accredited" and inserting "certified".

PURPOSE AND SUMMARY

The Mammography Quality Standards Reauthorization Act of 1998 reauthorizes programs for inspection and certification of mammography facilities. It also provides for direct patient notification of all mammography examinations, requiring that "a summary of the written report shall be provided to every patient in terms easily understood by a lay person;" and permits the Food and Drug Administration (FDA) to conduct a limited demonstration project to determine the feasibility of inspecting high-performing mammography facilities on a less than annual basis.

The Mammography Quality Standards Reauthorization Act of 1998, H.R. 4382, contains a number of provisions which go beyond the requirements of the Mammography Quality Standards Act of 1992. H.R. 4382:

Clarifies the responsibility of the mammography facility to retain mammogram records so that women have the ability to obtain the original of their mammograms;

Clarifies that both State and local government agencies have inspection authority;

Ensures that patients and referring physicians will be advised of any mammogram facility deficiencies;

Mandates direct patient notification written in layman's terms; and

Permits the FDA to conduct a limited demonstration project to determine the feasibility of inspecting high-performing mammography facilities on a schedule less frequent than the current annual cycle.

BACKGROUND AND NEED FOR LEGISLATION

According to the May 8, 1998, testimony of the General Accounting Office (GAO) before the Subcommittee on Health and Environment (see GAO/T-HEHS-98-164), breast cancer is the most commonly diagnosed non-skin cancer and the second leading cause of cancer deaths among American women. Experts estimate that during the 1990s as many as 1.8 million women will be diagnosed with breast cancer, and 500,000 will die from it. An estimated 44,000 women died from breast cancer in 1997 and an estimated 180,200 new cases of the disease were diagnosed. The probability of survival, as well as use of breast-conserving therapy and the avoidance of mastectomy, increases significantly when the disease is discovered in its early stages. Presently, the most effective technique for early detection of breast cancer is screening mammography, an X-ray procedure that can detect small tumors and breast abnormalities up to 2 years before they can be detected by touch. Over

90 percent of these early stage cancers can be cured, according to the FDA. The use of mammography as a tool for detecting early cancer continues to increase. When surveyed, the percentage of women aged 50 and older who had reported receiving mammograms in the previous year increased from 26 percent in 1987 to 57 percent in 1995, according to the Centers for Disease Control and Prevention (CDC). The percentage of women aged 40 to 49 who received mammograms in the five years prior to 1995 increased from 59 percent to 66 percent.

The authorization for the original legislation expired at the end of Fiscal Year 1997. Progress made in combating breast cancer is ascribed in part to the success of the Mammography Quality Standards Act of 1992 (Public Law 102-539) (MQSA). Many organizations, including the following, expressly support reauthorization of MQSA: the American Cancer Society, the National Coalition for Cancer Survivorship, the National Breast Cancer Coalition, the National Alliance of Breast Cancer Organizations, the Y-ME National Breast Cancer Organization, the Breast Cancer Resource Committee, the Susan G. Komen Foundation, the Women's Legal Defense Fund, the American College of Radiology, the American College of Obstetricians and Gynecologists, the American Registry of Diagnostic Medical Sonographers, the American Institute of Ultrasound in Medicine, and the Conference of Radiation Control Program Directors.

MAMMOGRAPHY QUALITY STANDARDS ACT OF 1992

In response to concerns about the safety, accuracy, and overall quality of mammography services, the 102nd Congress enacted the Mammography Quality Standards Act of 1992. The provisions of MQSA are found in Section 354 of the Public Health Service Act. Under this legislation, no mammography facility (as defined by the legislation) may operate in the United States after October 1, 1994, without certification by the Secretary of the Department of Health and Human Services (HHS) as having met HHS-established program requirements. To obtain certification, mammography facilities must be accredited by an HHS-approved body (the four current accreditation bodies are the American College of Radiology and the States of Iowa, Arkansas, and California). This entails passing an evaluation of clinical images from a facility and compliance with national regulations for personnel, equipment, quality assurance, and notification of examination results to patients. To maintain certification status, facilities must show continued compliance with the regulations during annual inspections and through reaccreditation every three years. Various sanctions are authorized under the Act and may be imposed by either HHS or a State on a facility that is found not to be in compliance with MQSA's requirements.

MQSA established national, uniform quality standards for mammography. These standards require that facilities:

Use only radiological technologists and equipment designed for mammography;

Employ only qualified physicians to interpret the results of the mammograms;

Establish a quality assurance and control program to ensure the reliability, clarity, and accurate interpretation of mammograms;

Undergo inspections by qualified inspectors on an annual basis; and

Be accredited by an HHS-approved accrediting organization.

Additionally, MQSA directed the Secretary of HHS to establish tough sanctions for any facility not following the standards. Finally, the Act provided adequate funding for accrediting organizations to ensure that all facilities can be certified and inspected.

The FDA has the responsibility for implementing and enforcing MQSA. On December 21, 1993, the agency set forth standards for accreditation and certification that mammography professionals and facilities would have to meet by October 1, 1994, or be banned from performing mammography. Final rules were developed with the advice of the National Mammography Quality Assurance Advisory Committee (composed of consumer and medical representatives) and were published on October 28, 1997, 62 Fed. Reg. 55852. The rules become effective on April 28, 1999. The Agency for Health Care Policy and Research (AHCPR) has also issued formal Mammography Clinical Practice Guidelines. See AHCPR Guideline Number 13, October 1994.

Costs of the program related to annual inspections may be covered through the collection of fees from mammography facilities. As of 1997, FDA charged $1,178 for the first mammography unit and $152 for each additional unit. Funding for other activities required under MQSA is available through an authorization of appropriations for "such sums as may be necessary" for Fiscal Year 1993 through Fiscal Year 1997.

The effectiveness of mammography as a cancer detection technique is directly related to the quality of mammography procedures. As of 1997, there were 10,025 certified mammography facilities in the United States, of which 9,687 were fully certified. The remainder were provisionally certified while they were in the process of becoming accredited or reinstated. The names and locations of certified facilities are available from the Cancer Information Service at the toll-free number of the National Cancer Institute, 1–800–4–CANCER. Additionally, all certified facilities are issued a certificate by the FDA which must be prominently displayed and which must be made available for examination upon request.

GAO'S ASSESSMENT OF THE MQSA PROGRAM

As required by MQSA, GAO published two interim reports (October 1995 and January 1997) and a final report (October 1997) on the program established by the FDA to implement the requirements of the Act. The first interim report focused on the Act's initial impact on access to and quality of mammography services and the second focused on FDA's annual inspection program. In short, GAO found that MQSA has increased mammography facilities' adherence to accepted quality assurance standards, which has, in turn, had a favorable effect on mammography services. The GAO also concluded that MQSA's establishment of nationwide minimum standards and required facility accreditation, resulted in thousands of facilities having to improve their quality assurance processes.

FDA's annual inspections of facilities, now in their third year, continue to show increasing compliance with these national quality standards. GAO found further evidence of improvement in the quality of the X-ray images. Before the Act took effect, 11 percent of facilities tested were unable to pass image quality tests; now, due to the heightened scrutiny under MQSA, the nationwide failure rate for passing image quality tests is only two percent.

When Congress enacted MQSA, concern was expressed that some women might have difficulty obtaining mammography services if facilities chose to close down rather than to upgrade their operations to meet the new quality standards. GAO found no indication that access problems had developed as a result of MQSA. Nationwide, the number of facilities that stopped offering mammograms was nearly offset by the number of new entrants into the field.

HEARINGS

The Subcommittee on Health and Environment held a hearing on May 8, 1998, on the "Reauthorization of the Mammography Quality Standards Act." The Subcommittee received testimony from the following witnesses: Dr. D. Bruce Burlington, Director, Center for Devices and Radiological Health, Food and Drug Administration, accompanied by Ms. Florence Houn, Director, Division of Mammography Quality and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration; Ms. Judy M. Destouet on behalf of the American College of Radiology; Ms. Amy S. Langer, Executive Director, National Alliance of Breast Cancer Organizations; Ms. Marsha Lillie-Blanton, Associate Director, Health Services, Quality, and Public Health Issues, General Account Office, accompanied by Mr. Frank Pasquier, Assistant Director, Health Services, Quality, and Public Health Issues, General Accounting Office; Mr. Robert A. Smith, Senior Director, Cancer Detection and Treatment, American Cancer Society; and Ms. Frances M. Visco, President, National Breast Cancer Coalition.

COMMITTEE CONSIDERATION

On August 3, 1998, the Subcommittee on Health and Environment met in open markup session to consider a Committee Print entitled the "Mammography Quality Standards Reauthorization Act of 1998." By a voice vote, the Subcommittee agreed to the Committee Print, amended, and approved the introduction of a clean bill for Full Committee consideration. The clean bill was introduced in the House on August 3, 1998, as H.R. 4382. On August 5, 1998, the Full Committee on Commerce met in open markup session and ordered H.R. 4382, the Mammography Quality Standards Reauthorization Act of 1998, reported to the House, amended, by a voice vote, a quorum being present.

ROLLCALL VOTES

Clause 2(l)(2)(B) of rule XI of the Rules of the House requires the Committee to list the recorded votes on the motion to report legislation and amendments thereto. There were no recorded votes taken in connection with ordering H.R. 4382 reported. An en bloc amendment offered by Mr. Bilirakis making technical and clarify-

ing corrections was adopted by a voice vote. A motion by Mr. Bliley to order H.R. 4382 reported to the House, amended, was agreed to by a voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee held a legislative hearing on May 8, 1998, and made findings that are reflected in this report.

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform and Oversight.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, the Committee finds that H.R 4382, the Mammography Quality Standards Reauthorization Act of 1998, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 14, 1998.

Hon. TOM BLILEY,
Chairman, Committee on Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4382, the Mammography Quality Standards Reauthorization Act of 1998, as ordered reported by the Committee on Commerce on August 5, 1998.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff is Julia Christensen.

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

H.R. 4382—Mammography Quality Standards Reauthorization Act of 1998

Summary: H.R. 4382 would reauthorize Mammography Quality Standards Act (MQSA) programs through fiscal year 2002. CBO estimates that enacting H.R. 4382 would increase federal government spending by $15 million in fiscal year 1999 and by $79 million over the 1999–2003 period. The bill would also reduce federal revenues by about $1 million in 1999 and by $5 million over the 1999–2003 period, assuming an enactment date of October 1, 1998.

Almost all of the increase in spending would be for the reauthorized programs that are subject to appropriation. In addition, the bill would require facilities performing mammograms to send written summaries of test results to all patients, which would both increase costs for federal health facilities that perform mammograms and also result in higher costs for Medicaid and the Federal Employees Health Benefits Program (FEHBP). CBO estimates that the increase in direct spending for Medicaid and FEHBP would total less than $1 million annually. This provision would also reduce federal revenues because it would raise the costs of employer-sponsored health insurance, and correspondingly reduce the amount of employee compensation subject to income and payroll taxes. Because the bill would affect direct spending and receipts, pay-as-you-go procedures would apply.

The requirement that mammogram facilities provide patients with easily understandable written summaries of their test results would also constitute an intergovernmental and private-sector mandate as defined in the Unfunded Mandates Reform Act of 1995 (UMRA). CBO estimates that the costs to state, local, and tribal governments of complying with this mandate would not exceed the threshold for intergovernmental mandates established in the law ($50 million in 1996, adjusted annually for inflation). Likewise, CBO estimates that the cost of this new requirement to the private sector would not exceed the applicable threshold ($100 million in 1996, adjusted annually for inflation).

Estimated cost to the Federal Government: The estimated budgetary impact of the H.R. 4382 is shown in the following table. The costs of this legislation fall within budget function 550 (Health).

[By fiscal year, in millions of dollars]

	1998	1999	2000	2001	2002	2003
SPENDING SUBJECT TO APPROPRIATION						
Spending under current law						
Budget Authority[1]	17	0	0	0	0	0
Estimated Outlays	17	3	1	0	0	0
Proposed changes:						
Authorization Level	0	18	19	20	20	0
Estimated Outlays	0	15	18	19	20	4
Spending under H.R. 4382:						
Authorization level	17	18	19	20	20	0
Estimated outlays	17	18	19	19	20	4
CHANGES IN DIRECT SPENDING						
Estimated budget authority	0	1	1	1	1	1
Estimated outlays	0	1	1	1	1	1

[By fiscal year, in millions of dollars]

	1998	1999	2000	2001	2002	2003
CHANGES IN REVENUES						
Estimated revenues	0	−1	−1	−1	−1	−1

[1] The 1998 level is the amount appropriated for that year.

This estimate assumes that H.R. 4382 is enacted on October 1, 1998.

Basis of estimate: For the purposes of this estimate, CBO assumed that all amounts authorized in the bill would be appropriated by the start of each fiscal year and that outlays would follow historical spending patterns.

Spending subject to appropriation: H.R. 4382 would reauthorize the Mammography Quality Standards Act through 2002, with some slight modifications to current law. Section 2 would authorize the breast cancer screening surveillance research grant program, administered by the National Cancer Institute, at a cost of almost $4 million in 1999 and $15 million over the 1999–2003 period. This program, operated jointly with the Centers for Disease Control and Prevention and the Department of Defense, funds research to determine the cost and effectiveness of screening programs in reducing breast cancer mortality.

Section 2 would also reauthorize funding for program activities that are not supported by the MQSA user fees. These activities include administering mammography facilities, providing consumer education, and establishing standards for accreditation bodies, equipment, personnel, and quality assurance. This provision would increase authorizations of appropriations for the MQSA program by $14 million in 1999 and by $59 million over the 1999–2003 period.

Section 6 of the bill would require facilities providing mammograms to send each patient a written and easily understandable summary of the results of her mammogram. CBO's earlier estimate of draft MQSA reauthorization language for S. 537—dated October 23, 1997—was prepared before the issuance of the final regulations implementing MQSA. This estimate assumes that additional facilities have implemented systems of written notification over the past year to comply with the final rule requiring a notification system of some form, thereby lowering CBO's estimate of the aggregate cost of the provision.

The Food and Drug Administration (FDA) estimates that about 40 million mammograms were performed in 1997, and the number is expected to increase over time. In cases where patients are not already provided with written summaries of the results of their mammograms, CBO estimates that enactment of this provision would cost health plans and providers an additional $1 per mammogram, on average. As a result, the cost to federal programs operating facilities that perform mammograms, such as the Indian Health Service, would increase by less than $1 million a year.

Section 7 would permit FDA inspectors to enter any mammography facility to determine compliance with MQSA certification requirements. Under current law, the agency is authorized to enter only certified facilities. According to the FDA, only a small number of unlicensed mammography facilities are operational; therefore, the agency would have to conduct few additional inspections under the proposal. Based on data provided by the FDA, CBO estimates

that this provision would increase federal costs by less than $1 million annually. Section 8 would allow the Secretary of Health and Human Services (HHS) to set up an open-ended demonstration program that allows certain well-run facilities to undergo less frequent inspections than currently required by law. CBO assumed the selected facilities would be subject to biannual inspections. (Current law requires each facility be inspected annually.) CBO assumed that 150 facilities would participate in the first year of the demonstration program. This estimate assumes implementation of the demonstration program would begin on October 1, 2001, with preparations starting in fiscal year 1999.

Current law directs the Secretary of HHS to assess an inspection fee on facilities—other than governmental entities as defined by statute—to cover the aggregate costs of the inspection program in each fiscal year. (The cost of inspecting governmental entities is paid through federal funds appropriated to the FDA.) Current law requires that the fee be reasonably based on the proportion of inspection costs related to each facility. However, section 8 would allow the estimated 150 facilities participating in the demonstration program to forgo a cycle of inspections during fiscal year 2002. During that year, CBO assumed that these facilities would not be required to pay any fee in lieu of the inspection fee to the MQSA program.

Current law effectively caps inspection fees for facilities at their reasonable prorated share of running the MQSA inspection program and disallows cross subsidization of the costs of the program among facilities. As a result, section 8 would have the effect of either decreasing the collections of fees available to operate their inspection program or requiring an increase in authorizations of appropriations to continue the MQSA inspection program as it is currently operated.

This estimate assumes that resources associated with the MQSA inspection program, such as the inspector workforce, would be maintained at current levels over the 1999–2003 period. The demonstration program described in section 8 would increase authorizations of appropriations for the MQSA program by less than $1 million over the 1999–2003 period. This amount would cover the portion of the costs of maintaining the inspection program attributable to the demonstration program participants during the off-inspection year (excepting the expenses related to forgone field inspections) plus the cost of running the demonstration program through fiscal year 2003.

Because of the open-ended nature of the demonstration program, its cost to the federal government would climb under the bill as the number of facilities participating rose over time. Increased participation would create a wedge in the shares of inspection program costs borne by facilities exempted from inspection fees in the years they are not inspected and by facilities that continue to be inspected annually. Such an arrangement would transfer a growing share of the cost of the inspection program to the federal government through increases in authorizations of appropriations if current program resources were maintained and fees were not collected from the demonstration program participants to cover their reasonable share of program expenses in non-inspection years.

Direct spending and revenues: As noted earlier, requiring facilities to send written summaries of mammogram results directly to patients would cost health plans and providers an additional $1 per mammogram, on average. This requirement would increase costs for Medicaid and FEHBP by less than $1 million annually. (CBO assumes these costs to the federal government would extend beyond the expiration of the MQSA program because health plans and providers would continue to provide these reports to patients and would incur costs.) Medicare spending would not be significantly affected, because almost all payments for mammograms are based on a fee schedule.

Higher costs for health plans and providers would also increase premiums for employer-sponsored health insurance, with a corresponding reduction in the amount of employee compensation subject to income and payroll taxes. The Joint Committee on Taxation estimates that income and payroll tax revenues would fall by about $1 million a year.

Pay-as-you-go considerations: The Balanced Budget and Emergency Deficit Control Act of 1985 sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. Because section 6 of the bill would affect direct spending and receipts, pay-as-you-go procedures would apply. The impact of this provision on Medicaid and FEHBP outlays and on federal revenues is shown in the table below. For purposes of enforcing pay-as-you-go procedures, only the effects in the budget year and the succeeding four years are counted.

[By fiscal year, in millions of dollars]

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Changes in outlays	0	1	1	1	1	1	1	1	1	1	1
Changes in receipts	0	−1	−1	−1	−1	−1	−1	−1	−1	−1	−1

Estimated impact on State, local, and tribal governments: The requirement that mammogram facilities provide patients with easily understandable written summaries of their test results would constitute a mandate as defined by the Unfunded Mandates Reform Act. Based on survey and statistical data provided by the Food and Drug Administration and professional health care associations, CBO estimates that state, local and tribal medical facilities that perform mammograms would face additional costs of approximately $3 million annually during the first five years of implementation. The costs would include the initial development or purchase of a classification and reporting system, its implementation, and other operational costs. As noted earlier in the explanation of federal costs, these costs are lower than CBO's earlier estimate of draft MQSA reauthorization language (dated October 23, 1997). Since then, CBO has received updated information about the proportion of facilities that are governmentally operated and about the number of facilities that currently provide written reports.

States would face additional Medicaid costs of less than $1 million annually as a result of the notification requirements. However, because states have sufficient flexibility to alter their financial or programmatic responsibilities to offset these costs, the requirement would not be a mandate as defined by UMRA. The bill would also

allow the Secretary of Health and Human Services to require certain mammogram facilities to notify patients if the quality of care in those facilities is found to fall short of existing statutory standards. Facilities would be free from the responsibility to make such notifications, however, if they are in compliance with the underlying standards. Consequently, this provision would not be considered a mandate under UMRA.

Finally, the bill would allow local governments to be approved to inspect mammogram facilities. Local governments, like states, would receive federal reimbursements for the costs associated with the inspections.

Estimated impact on the private sector: The requirement to directly send patients written summaries of their test results would also constitute a mandate on the over 9,000 private sector facilities in the U.S. that perform mammograms. These facilities include hospitals, outpatient departments, clinics, radiology practices, mobile units, and physicians' offices. CBO estimates that the direct cost of this requirement on these private sector entities would not exceed the threshold for private-sector mandates specified in UMRA ($100 million in 1996, adjusted annually for inflation) in any of the first five years the mandate would be effective.

Estimate prepared by: Federal cost estimate: Julia Christensen; Impact on State, local, and tribal governments: Leo Lex; Impact on the private sector: Julia Christensen.

Estimate approved by: Paul N. Van de Water, Assistant Director for Budget Analysis Division.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates the short title as the "Mammography Quality Standards Reauthorization Act of 1998."

Section 2. Authorization of appropriations

Section 2 authorizes the Mammography Quality Standards Act through Fiscal Year 2002, and makes a technical amendment.

Section. 3. Application of current version of appeal regulations

Section 3 makes a technical amendment to the present statute.

Section 4. Accreditation standards

Section 4 clarifies that physicians employed in reviewing mammography facilities ("review physicians") may not have any conflicting relationships that may interfere with an even-handed review. This section permits the Secretary of HHS to impose additional requirements on review physicians through an accreditation body.

Section 5. Clarification of facilities responsibility to retain mammogram records

Section 5 clarifies that mammography facilities shall maintain permanent medical records of their patients for not less than five years, or not less than ten years if no subsequent mammograms are performed at the same facility. This section permits State law to require longer periods of time, and also permits the patient to transfer the mammogram record to another medical institution, a physician, or the patient herself.

Section 6. Direct reports to patients

Section 6 provides that all mammography patients receive a written summary of the mammography report in language easily understood by a lay person. A similar provision in the Mammography Quality Standards Act of 1992 provided for direct patient notification for self-referred women. H.R. 4382 broadens the scope to require direct patient notification to all mammography patients.

In October 1994, the U.S. Department of Health and Human Services Agency for Health Care Policy and Research published "Quality Determinants of Mammography," Clinical Practice Guideline Number 13. According to this guideline, "Any written communication must have language that is carefully constructed to impart results without causing undue anxiety, to promote a relationship between the woman and a health care provider, and to encourage the woman to take the next step." The Committee envisions that this written notification need not be any more detailed than the examples that appear in the "Quality Determinants of Mammography." Chapter Four of this publication, which contains sample letters, is reprinted as an appendix to this report. In the interests of timely compliance of mammography facilities, the Committee anticipates that this new requirement will not be obligatory until April 28, 1999, the day the final regulations for Quality Mammography Standards go into effect pursuant to the final rule published

by HHS in the Federal Register on October 28, 1997, 62 Fed. Reg. 55852.

Section 7. Scope of inspections

Section 7 clarifies that the Secretary of HHS may inspect both certified and uncertified facilities to monitor compliance with certification requirements.

Section 8. Demonstration program regarding frequency of inspections

Section 8 authorizes the Secretary of HHS to undertake a demonstration project that may reduce the inspection burden by reducing the inspection frequency on those mammography facilities of the highest quality. The Committee anticipates that such a demonstration project would be large enough to produce sufficient, reliable data, but should not cover more than three to five States.

Although the demonstration project may not be implemented before April 1, 2001, the Committee encourages the Secretary to begin preparations well before this date so the program can begin on or immediately after the statutory date. The Committee believes that a focus of the limited resources available for this program on those facilities having the greatest difficulty meeting the quality standards will provide the greatest benefit to the public health of women receiving the benefits of mammography.

Section 9. Clarification of authority to delegate inspection responsibility to local government agencies

Section 9 clarifies that local governments may be delegated inspection authority.

Section 10. Patient notification concerning health risks

Section 10 requires that substandard mammography facilities notify their patients of the deficiencies presenting significant health risks.

Section 11. Requirement to comply with information requests

Section 11 clarifies that the requirements to comply with information requests apply to those requests originating from accrediting bodies as well as the Secretary of HHS.

Section 12. Adjustment to severity of sanctions

Section 12 adjusts the severity of sanctions so that the necessary findings include intentional failures or failures that would place human health at serious risk.

Section 13. Technical amendment

Section 13 makes a technical amendment.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted

is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

SECTION 354 OF THE PUBLIC HEALTH SERVICE ACT

SEC. 354. CERTIFICATION OF MAMMOGRAPHY FACILITIES.

(a) DEFINITIONS.—As used in this section:

(1) * * *

* * * * * * *

(4) INSPECTION.—The term "inspection" means an onsite evaluation of the facility by the Secretary, or State *or local* agency on behalf of the Secretary.

* * * * * * *

(8) REVIEW PHYSICIAN.—The term "review physician" means a physician as prescribed by the Secretary under subsection (f)(1)(D) who meets such additional requirements as may be established by an accreditation body under subsection (e) and approved by the Secretary to review clinical images under subsection (e)(1)(B)(i) on behalf of the accreditation body.

* * * * * * *

(d) APPLICATION FOR CERTIFICATE.—

(1) * * *

(2) APPEAL.—If the Secretary denies an application for the certification of a facility submitted under paragraph (1)(A), the Secretary shall provide the owner or lessor of the facility or the agent of the owner or lessor who submitted such application—

(A) a statement of the grounds on which the denial is based, and

(B) an opportunity for an appeal in accordance with the procedures set forth in regulations of the Secretary published at [42 C.F.R. 498 and in effect on the date of the enactment of this section] *part 498 of title 42, Code of Federal Regulations*.

* * * * * * *

(e) ACCREDITATION.—

(1) APPROVAL OF ACCREDITATION BODIES.—

(A) * * *

(B) STANDARDS.—The Secretary shall establish standards for accreditation bodies, including—

(i) standards that require an accreditation body to perform—

(I) a review of clinical images from each facility accredited by such body not less often than every 3 years which review will be made by qualified [practicing] *review* physicians; and

(II) a review of a random sample of clinical images from such facilities in each 3-year period beginning October 1, 1994, which review will be made by qualified [practicing] *review* physicians;

(ii) standards that prohibit individuals conducting the reviews described in clause (i) from maintaining

any [financial] relationship to the facility undergoing review which would constitute a conflict of interest;

* * * * * * *

(f) QUALITY STANDARDS.—

(1) IN GENERAL.—The standards referred to in subsection (d)(1)(B)(i) are standards established by the Secretary which include—

(A) * * *

* * * * * * *

(G) a requirement that—

[(i) a facility that performs any mammogram maintain the mammogram in the permanent medical records of the patient—

[(I) for a period of not less than 5 years, or not less than 10 years if no additional mammograms of such patient are performed at the facility, or longer if mandated by State law; or

[(II) until such time as the patient should request that the patient's medical records be forwarded to a medical institution or a physician of the patient;

whichever is longer; and]

(i) a facility that performs any mammogram—

(I) except as provided in subclause (II), maintain the mammogram in the permanent medical records of the patient for a period of not less than 5 years, or not less than 10 years if no subsequent mammograms of such patient are performed at the facility, or longer if mandated by State law; and

(II) upon the request of or on behalf of the patient, transfer the mammogram to a medical institution, to a physician of the patient, or to the patient directly; and

(ii)(I) a facility must assure the preparation of a written report of the results of any mammography examination signed by the interpreting physician;

* * * * * * *

[(IV) if such report is sent to the patient, the report shall include a summary written in terms easily understood by a lay person; and]

(IV) whether or not such a physician is available or there is no such physician, a summary of the written report shall be sent directly to the patient in terms easily understood by a lay person; and

* * * * * * *

(g) INSPECTIONS.—

(1) ANNUAL INSPECTIONS.—

(A) IN GENERAL.—The Secretary may enter and inspect [certified] facilities to determine compliance with *the certification requirements under subsection (b) and* the standards established under subsection (f). The Secretary shall,

if feasible, delegate to a State *or local* agency the authority to make such inspections.

(B) IDENTIFICATION.—The Secretary, or State *or local* agency acting on behalf of the Secretary, may conduct inspections only on presenting identification to the owner, operator, or agent in charge of the facility to be inspected.

(C) SCOPE OF INSPECTION.—In conducting inspections, the Secretary or State *or local* agency acting on behalf of the Secretary—

(i) shall have access to all equipment, materials, records, and information that the Secretary or State *or local* agency considers necessary to determine whether the facility is being operated in accordance with this section; and

(ii) may copy, or require the facility to submit to the Secretary or the State *or local* agency, any of the materials, records, or information.

(D) QUALIFICATIONS OF INSPECTORS.—Qualified individuals, as determined by the Secretary, shall conduct all inspections. The Secretary may request that a State *or local* agency acting on behalf of the Secretary designate a qualified officer or employee to conduct the inspections, or designate a qualified Federal officer or employee to conduct inspections. The Secretary shall establish minimum qualifications and appropriate training for inspectors and criteria for certification of inspectors in order to inspect facilities for compliance with subsection (f).

(E) FREQUENCY.—The Secretary or State *or local* agency acting on behalf of the Secretary shall conduct inspections under this paragraph of each facility not less often than annually*, subject to paragraph (6)*.

(F) RECORDS AND ANNUAL REPORTS.—The Secretary or a State *or local* agency acting on behalf of the Secretary which is responsible for inspecting mammography facilities shall maintain records of annual inspections required under this paragraph for a period as prescribed by the Secretary. Such a State *or local* agency shall annually prepare and submit to the Secretary a report concerning the inspections carried out under this paragraph. Such reports shall include a description of the facilities inspected and the results of such inspections.

* * * * * * *

(3) INSPECTION OF FACILITIES INSPECTED BY STATE *OR LOCAL* AGENCIES.—The Secretary shall inspect annually facilities inspected by State *or local* agencies acting on behalf of the Secretary to assure a reasonable performance by such State *or local* agencies.

(4) TIMING.—The Secretary, or State *or local* agency, may conduct inspections under paragraphs (1), (2), and (3), during regular business hours or at a mutually agreeable time and after providing such notice as the Secretary may prescribe, except that the Secretary may waive such requirements if the

continued performance of mammography at such facility threatens the public health.

* * * * * * *

(6) DEMONSTRATION PROGRAM.—

(A) IN GENERAL.—The Secretary may establish a demonstration program under which inspections under paragraph (1) of selected facilities are conducted less frequently by the Secretary (or as applicable, by State or local agencies acting on behalf of the Secretary) than the interval specified in subparagraph (E) of such paragraph.

(B) REQUIREMENTS.—Any demonstration program under subparagraph (A) shall be carried out in accordance with the following:

(i) The program may not be implemented before April 1, 2001. Preparations for the program may be carried out prior to such date.

(ii) In carrying out the program, the Secretary may not select a facility for inclusion in the program unless the facility is substantially free of incidents of noncompliance with the standards under subsection (f). The Secretary may at any time provide that a facility will no longer be included in the program.

(iii) The number of facilities selected for inclusion in the program shall be sufficient to provide a statistically significant sample, subject to compliance with clause (ii).

(iv) Facilities that are selected for inclusion in the program shall be inspected at such intervals as the Secretary determines will reasonably ensure that the facilities are maintaining compliance with such standards.

(h) SANCTIONS.—

(1) * * *

(2) PATIENT INFORMATION.—If the Secretary determines that the quality of mammography performed by a facility (whether or not certified pursuant to subsection (c)) was so inconsistent with the quality standards established pursuant to subsection (f) as to present a significant risk to individual or public health, the Secretary may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the Secretary may require.

[(2)**]** *(3)* CIVIL MONEY PENALTIES.—The Secretary may assess civil money penalties in an amount not to exceed $10,000 for—

(A) failure to obtain a certificate as required by subsection (b),

(B) each failure by a facility to substantially comply with, or each day on which a facility fails to substantially comply with, the standards established under subsection (f) or the requirements described in subclauses (I) through (III) of subsection (d)(1)(B)(ii), **[**and**]**

(C) each failure to notify a patient of risk as required by the Secretary pursuant to paragraph (2), and

[(C)] *(D)* each violation, or for each aiding and abetting in a violation of, any provision of, or regulation promulgated under, this section by an owner, operator, or any employee of a facility required to have a certificate.

[(3)] *(4)* PROCEDURES.—The Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under paragraphs (1) [and (2)] *through (3)*. Such procedures shall provide for notice to the owner or operator of the facility and a reasonable opportunity for the owner or operator to respond to the proposed sanctions and appropriate procedures for appealing determinations relating to the imposition of sanctions.

(i) SUSPENSION AND REVOCATION.—

(1) IN GENERAL.—The certificate of a facility issued under subsection (c) may be suspended or revoked if the Secretary finds, after providing, except as provided in paragraph (2), reasonable notice and an opportunity for a hearing to the owner or operator of the facility, that the owner, operator, or any employee of the facility—

(A) * * *

* * * * * * *

(C) has failed to comply with reasonable requests of the Secretary *(or of an accreditation body approved pursuant to subsection (e))* for any record, information, report, or material that the Secretary *(or such accreditation body or State carrying out certification program requirements pursuant to subsection (q))* concludes is necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards established under subsection (f);

(D) has refused a reasonable request of the Secretary, any Federal officer or employee duly designated by the Secretary, or any State *or local* officer or employee duly designated by the State *or local agency*, for permission to inspect the facility or the operations and pertinent records of the facility in accordance with subsection (g);

* * * * * * *

(2) ACTION BEFORE A HEARING.—

(A) IN GENERAL.—The Secretary may suspend the certificate of the facility before holding a hearing required by paragraph (1) if the Secretary [makes the finding described in paragraph (1) and determines that—

[(i) the failure of a facility to comply with the standards established by the Secretary under subsection (f) presents a serious risk to human health; or

[(ii) a facility has engaged in an action described in subparagraph (D) or (E) of paragraph (1).]

has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that—

(i) the failure or violation was intentional; or

(ii) the failure or violation presents a serious risk to human health.

* * * * * * *

(q) STATE PROGRAM.—

(1) * * *

* * * * * * *

(4) WITHDRAWAL OF APPROVAL.—

(A) * * *

(B) EFFECT OF WITHDRAWAL.—If the Secretary withdraws the approval of a State under subparagraph (A), the certificate of any facility [accredited] *certified* by the State shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain certification by the Secretary.

(r) FUNDING.—

(1) * * *

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

(A) to award research grants under subsection [(q)] *(p)*, such sums as may be necessary for each of the fiscal years 1993 through [1997] *2002*; and

(B) for the Secretary to carry out other activities which are not supported by fees authorized and collected under paragraph (1), such sums as may be necessary for fiscal [year] *years* 1993 through [1997] *2002*.

APPENDIX


Clinical Practice Guideline
Number 13
Quality Determinants of Mammography
U.S. Department of Health and Human Services
Public Health Service
Agency for Health Care Policy and Research
Clinical Practice Guideline
Quality Mammography

Clinical Practice Guideline
Number 13

Quality Determinants of Mammography

Quality Determinants of Mammography Guideline Panel

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Public Health Service
Agency for Health Care Policy and Research
Rockville, Maryland

AHCPR Publication No. 95-0632
October 1994

4 Activities After the Examination

Communicating Results

RECOMMENDATION: The referring health care provider and the interpreting physician should be sensitive, supportive, and appropriate in communicating results, as well as prompt and accurate. (B)

STRONG RECOMMENDATION: An appropriate professional at the mammography facility, usually an interpreting physician, should send the woman's health care provider a written report documenting the specific findings, followup recommendations, and the name of the interpreting physician. The facility should directly telephone the referring provider if the result is suspicious for cancer. (B)

STRONG RECOMMENDATION: The mammography facility personnel should give the woman written notification of the results of her mammography and other breast imaging, either on site or by mail. The results should be in simple language, document the name of the interpreting physician, be given in a timely fashion, and include further steps to be taken. (B)

RECOMMENDATION: If a facility accepts women who have no health care provider, facility personnel should give the woman a list of qualified providers who are willing to provide care. The name, address, and phone number of the provider chosen should be recorded, if possible. (C)

STRONG RECOMMENDATION: The facility personnel should directly telephone the woman who has no health care provider if the result is suspicious for cancer. (B)

Many women believe that mammography results are normal if they are not contacted after their examination. This impression that "no news is good news" can have serious adverse consequences for women with an abnormal examination. The interpreting physician, the referring health care provider, and the woman are all responsible for ensuring that mammography results are communicated in an effective and timely manner and that recommendations are carried out. Timely communication is necessary whether results are normal or abnormal (Table 3).

An increasing number of mammography facilities have begun to report both normal and abnormal results directly to the woman. This can be accomplished without disrupting the woman's relationship with her referring provider. Studies have shown that direct communication of results to the woman by the mammography facility produces a dramatic improvement in compliance with followup recommendations (Cardenosa

Table 3. Reporting of results by mammography facility

[illegible]	Communication to women		Communication to health care provider in addition to standard report	Always necessary written report to health care provider
	Oral (on site or [illegible])	Written (on site or sent by mail)		
Normal	Optional	Strongly recommended	None	Strongly recommended
Abnormal: schedule additional imaging and/or ultrasonography				
a) On line[1]	Recommended[2]	Strongly recommended[2]	Recommended[3]	Strongly recommended
b) Off line[1]	Optional[2]	Strongly recommended[2]	Recommended[3]	Strongly recommended
Abnormal: short-interval followup	Optional	Strongly recommended	Optional	Strongly recommended
Abnormal: biopsy	Optional, strongly recommended for self-referred women	Strongly recommended[4]	Strongly recommended	Strongly recommended

[1]For an online study, the interpreting physician is present and reads the mammogram while the patient is there. For an offline study, the mammogram may be read after the woman leaves so the interpreting physician does not need to be present.
[2]For any patient for whom additional views or ultrasonography are recommended, a telephone call or discussion onsite with the patient may precede the written letter when the studies are to be performed immediately or within 2 days at that mammography facility. However, the results of the original and additional studies must be provided to the woman in writing.
[3]A telephone call from the mammography facility to the woman's designated physician or other health care provider is recommended. For self-referred patients, the telephone call should be made to the woman herself.
[4]For any patient without a direct referral, the mammography facility may wish to send the letter via registered or certified mail.

Note: Strong recommendations deal with elements of mammography that the panel considers essential to good practice. Recommendations deal with elements of mammography that the panel considers attainable in most but not all cases. Options are statements of a less compelling nature that cannot be justified as recommendations.

and Eklund, 1991; Monsees, Destouet, and Evens, 1988; Rubin, Frank, Stanley et al., 1990). To be most effective, results should be presented clearly and promptly (Aalders and Schade, 1991; Bird and McLelland, 1986; Dershaw, Liberman, and Lippin, 1992; Kessler, Rimer, Devine et al., 1991; Monsees, Destouet, and Evens, 1988; Rubin, Frank, Stanley et al., 1990). Traditional communication procedures, where the facility communicates only with the referring provider, result in inadequate compliance with followup recommendations (Robertson and Kopans, 1989).

Communicating normal results directly to the woman as soon as possible eliminates anxiety, reinforces the woman's role as a responsible participant in the process, reminds the woman of the importance of regular screening, and is a quality assurance safeguard. Effective communication is most crucial when results are abnormal and additional imaging or other followup is required. If findings are abnormal, the written results should detail steps the woman should take next.

Problems in communicating abnormal results have included confusion concerning the appropriate steps to be taken; inappropriate or insensitive communication, resulting in avoidable anxiety and confusion; delay in receipt of results; and failure to communicate results to the woman at all—for example, when reports are misfiled or filed unread. These problems have caused delays in diagnosis and treatment, with consequences that include limited treatment options and death (Brenner, 1992a and 1992b; De Neef and Gandara, 1991; Robertson and Kopans, 1989; Unger, 1990). Providing results directly to the woman is a sound risk-management procedure, reducing the prospect of medicolegal complications for both the interpreting physician and the referring health care provider (Rubin, Frank, Stanley et al., 1990).

Any written communication must have language that is carefully constructed to impart results without causing undue anxiety, to promote a relationship between the woman and a health care provider, and to encourage the woman to take the next step. Examples of letters communicating results directly to women are shown on the following pages. These are only examples. They should be adapted to local populations in a manner that is sensitive to cultural diversity and to prearranged protocols between the mammography facility and the referring provider. Examples of communication of normal results are shown in a short form in Sample Letter A and in a longer version in Sample Letters B (for a screening mammogram) and C (for a diagnostic mammogram). Examples of communication of an abnormal result with a recommendation for short-interval followup are shown in a brief form in Sample Letter D and a longer version in Sample Letter E. Examples of notification to women of abnormal results with a recommendation for additional imaging or biopsy are shown in brief form in Sample Letter D and in longer form in Sample Letters F and G.

Sample Letter A. Mammography facility to the woman with a normal result on a screening mammogram—short form

XYZ Mammography Facility
Street Address
City, State, and ZIP Code

_____ *(name of woman)*

We are pleased to tell you that the result of your mammogram on _____ *(date)* appears to be normal.

Please note: Mammography does not detect all breast cancer.

Regular breast exam by a doctor or other health care provider is an important part of good breast health care.

Contact your provider to evaluate any change in breast shape, nipple discharge, or breast lump.

Mammography facilities may accept self-requesting and self-referred women for mammography. Interpreting physicians have additional responsibilities for ensuring the effective communication of results for these women.

- *Self-requesting woman.* This woman comes for mammography on her own initiative but is able to name a personal physician or health care provider. Whether the woman is having screening or diagnostic mammography, the interpreting physician should document that the designated provider accepts responsibility for the woman's breast care before sending the mammography report. In cases where the provider declines to accept the mammography report from the mammography facility, the facility should treat the woman as if she were self-referred.
- *Self-referred woman.* This is a woman who comes for mammography but has no personal health care provider or for whom the provider declines responsibility. Whether the woman is having screening or diagnostic mammography, the interpreting physician assumes responsibility for the woman's breast care, including education, physical examination, and communication of mammography results directly to the patient in understandable language. Mammography facility personnel should give the woman a list of qualified providers. If the woman chooses a provider from a list provided by the mammography facility, the interpreting physician should ensure that the chosen clinician will assume responsibility for the woman's breast care. Although self-referral has improved access to mammography, it has increased the responsibilities of the interpreting physician and created more possibilities for failure to communicate abnormal results.

Sample Letter B. Mammography facility to the woman with a normal result on a screening mammogram

XYZ Mammography Facility
Street Address
City, State, and ZIP Code

Date

Ms. Woman Screened
1234 Main Street
Anytown, US 67890

Dear _____:

The result of your mammogram on _____ *(date)* appears to be normal. The next time you see your doctor or other health care provider, ask about when you should have your next mammogram. If you prefer (or if you do not have a doctor or other health care provider), you may call this office to make an appointment for your next mammogram. Your next mammogram should be done in _____ *(month/year)*.

By having a mammogram, you have taken an important step to promote your good health. But having a mammogram regularly is only one part of good breast care. Your doctor or other health care provider should examine your breasts as part of your regular physical examination. Monthly breast self-examination is also important.

Remember that you should never ignore a breast lump or any other change in your breasts, even if your mammogram is normal. If you find a lump or other change, talk to your health care provider about it as soon as possible.

If you change your doctor or other health care provider before your next mammogram, or if you have your next mammogram somewhere else, please pass on the information that you had a mammogram here on _____ *(date)*. Either your health care provider or the mammography facility may borrow your films from here if they need to see them.

Your mammogram was interpreted by Dr. _____. Results of the mammogram have been sent to _____ *(doctor, other health care provider, or clinic)*. Your films will be kept at _____ *(facility name, address, phone number)*.

Sample Letter C. Mammography facility to the woman with a normal result on a diagnostic mammogram

XYZ Mammography Facility
Street Address
City, State, and ZIP Code

Date

Ms. Woman Examined
1234 Main Street
Anytown, US 67890

Dear _____:

The result of your mammogram on _____ *(date)* appears to be normal. However, not all breast problems are detected by mammography alone. You had this mammogram because something in your breast indicated a possible problem. It is very important that your doctor or other health care provider look again at the possible problem area and decide whether you should have more tests done.

By having a mammogram, you have taken an important step to promote your good health. But having a mammogram regularly is only one part of good breast care. Your doctor or other health care provider should examine your breasts as part of your regular physical examination. Monthly breast self-examination is also important.

Remember that you should never ignore a breast lump or any other change in your breasts, even if your mammogram is normal. If you find a lump or other change, talk to your health care provider about it as soon as possible.

If you change your doctor or other health care provider before your next mammogram or if you have your next mammogram somewhere else, please pass on the information that you had a mammogram here on _____ *(date)*. Either your health care provider or the mammography facility may borrow your films from here if they need to see them.

Your mammogram was interpreted by Dr. _____. The mammogram results have been sent to _____ *(doctor, other health care provider, or clinic)*. Your films will be kept at _____ *(facility name, address, phone number)*.

Sample Letter D. Mammography facility to the woman with an abnormal result on a screening mammogram—short form

XYZ Mammography Facility
Street Address
City, State, and ZIP Code

_____ (name of woman)

The purpose of this letter is to make sure that you have been in contact with your doctor or other health care provider regarding your mammogram on _____ *(date)*. The mammogram showed findings that require further followup. If you have not already spoken to your provider, please call his or her office to discuss your results.

Interpreting Physician: _____

STRONG RECOMMENDATION: At the time of the examination, mammography facility personnel should inform all women of the time period in which they will receive their results and of the possibility that prior films may need to be obtained. The woman should also be instructed to call the mammography facility or her health care provider if she does not receive her results within the stated time period. The facility should report results to the woman's provider and to the woman within the shortest practical time period. (B)

RECOMMENDATION: The facility should use its best efforts to send a report to the referring health care provider and to send results to the woman as soon as possible, usually within 10 business days. The reporting period should not exceed 30 days. (B)

STRONG RECOMMENDATION: The interpreting physician or designee should telephone the results of an abnormal examination that requires needle or open biopsy to the referring (or designated) health care provider's office in a timely manner. (B)

RECOMMENDATION: The interpreting physician or designee should telephone the results of an abnormal examination that requires additional views and/or ultrasonography in a timely manner to the referring (or designated) health care provider's office. (B)

OPTION: The interpreting physician or the referring (or designated) health care provider may telephone the woman directly to explain abnormal findings, their significance, and recommended next steps. (B)

Sample Letter E. Mammography facility to the self-referred woman with an abnormal result for which short-interval followup is recommended

XYZ Mammography Facility
Street Address
City, State, and ZIP Code

Date

Ms. Woman Screened
1234 Main Street
Anytown, US 67890

Dear _____:

The result of your mammogram on _____ *(date)* shows an area in your *left/right* breast that needs to be looked at again in _____ months to make sure it is normal.

We have made an appointment for you to have your followup mammogram on _____ *(time, date)* at _____ *(location)*. We will *phone you/ send you a postcard* about 2 weeks before this date to remind you of the appointment. If for any reason you cannot keep this appointment, please call us to make another appointment.

By having a mammogram, you have taken an important step to promote your good health. But having a mammogram regularly is only one part of good breast care. Your doctor or other health care provider should examine your breasts as part of your regular physical examination. Monthly breast self-examination is also important.

Remember that you should never ignore a breast lump, even if your mammogram is normal. If you find a lump or any other change in your breasts, talk to your doctor or other health care provider about it as soon as possible.

If you change your doctor or other health care provider before your next mammogram, please pass on the information that you had a mammogram here on _____ *(date)*.

If you decide to go to another facility to have the followup mammogram, please tell the new facility that you had a mammogram here on _____ *(date)* and that the films are stored here. The new facility may wish to borrow the films stored here to compare them with the results of your followup mammogram. **Please phone our office and tell us if you decide to have your followup mammogram done at a different facility**.

Your mammogram was interpreted by Dr. _____. Results of the mammogram have been sent to _____ *(doctor, other health care provider, or clinic)*. Your films will be kept at _____ *(facility name, address, phone number)*.

If you have any questions, please call Dr. _____ or Dr. _____ at _____ *(phone number)*.

Sample Letter F. Mammography facility to the woman with an abnormal result for whom additional studies and/or ultrasonography are recommended

XYZ Mammography Facility
Street Address
City, State, and ZIP Code

Date

Ms. Woman Screened
1234 Main Street
Anytown, US 67890

Dear _____:

The result of your mammogram on _____ *(date)* shows a finding in your *left/right* breast that needs to be looked at further. This is not uncommon. In many cases, study of such findings shows that there is nothing to worry about.

We would like you to come back to have *a followup mammogram/an ultrasound examination.* Ultrasound is a routine procedure that is done when the mammogram suggests that a cyst is present. (A cyst is a small pouch filled with fluid.) The ultrasound examination takes very little time. No x-rays or breast compression are needed.

We have made an appointment for you to have your followup test on _____ *(time, date)* at _____ *(location).* If for any reason you cannot keep this appointment, please call us to make another appointment. *[OR:* Please call us within the next week at _____ *(phone number)* to make an appointment for this followup test.*]*

If you decide to go to another facility to have the followup test, please tell the new facility that you had a mammogram here on _____ *(date)* and that the films are stored here. The new facility may wish to borrow the films stored here to compare them with the results of your followup test. **Please phone our office and tell us if you decide to have your followup test done at a different facility.**

If you change your doctor or other health care provider, please pass on the information that you had a mammogram here on _____ *(date).*

Your mammogram was interpreted by Dr. _____. Results of the mammogram have been sent to _____ *(doctor, other health care provider, or clinic).* Your films will be kept at _____ *(facility name, address, phone number).*

If you have any questions, please call Dr. _____ or Dr. _____ at _____ *(phone number).*

Sample Letter G. Mammography facility to the woman with an abnormal result for which biopsy is recommended

XYZ Mammography Facility
Street Address
City, State, and ZIP Code

Date

Ms. Woman Screened
1234 Main Street
Anytown, US 67890

Dear _____:

The result of your mammogram on _____ *(date)* shows an abnormal area in your *left/right* breast that needs to be looked at further.

Please contact _____ *(health care provider named or selected at time of mammogram)* at _____ *(phone number)* to schedule an appointment as soon as possible. We notified _____ *(health care provider)* of the results of your mammogram on _____ *(date)*. It is important that you discuss these results with your doctor or other health care provider and decide together what the next steps in your medical care should be.

If we have already spoken with you by telephone, please consider this letter a reminder of our recommendation that you make an appointment with your health care provider on _____ *(date)*.

If you decide to consult a different doctor or other health care provider from the one listed here, please tell her/him that you had a mammogram here on _____ *(date)*. Also, please call us as soon as possible to tell us of your decision.

Your mammogram was interpreted by Dr. _____. Your films will be kept at _____ *(facility name, address, phone number)*.

If you have any questions or need any further assistance, please do not hesitate to call Dr. _____ or Dr. _____ at _____ *(phone number)*.

Mammography facility personnel should telephone the referring or designated health care provider because the written report may not reach the provider or may not arrive in time for the provider to respond to questions from the patient. A telephone call also enables the provider to ask questions about the report and to discuss followup options with the interpreting physician (Brenner, 1992b; Cardenosa and Eklund, 1991; Dershaw, Liberman, and Lippin, 1992; McLelland, 1987; Monsees, Destouet, and Evens, 1988; Robertson and Kopans, 1989; Rubin, Frank, Stanley et al., 1990).

When mammography results are abnormal, a telephone call to the woman's designated health care provider before a report is sent may identify and resolve any vagueness in the provider-patient status. For a self-requesting woman with an abnormal finding, this call will significantly reduce the chance that she will slip through the cracks.

If the woman does not have a provider or if the provider declines to accept the report, the interpreting physician or designee should call the woman directly to explain the result and the recommended next steps. This telephone communication is in addition to the written report and should offer the option to have the results explained in person. Information should not be left on an answering machine or given to another individual without the woman's express prior permission. Particularly for the woman without a referring provider, the mammography facility may choose to send written notification of abnormal results by certified mail or with return receipt requested. Mammography facility personnel should document the communication to the referring provider or the woman in the woman's medical record. Recommended reporting is outlined in Table 3. For more information on the communication responsibilities of the interpreting physician, see Chapter 6.

Followup, Tracking, and Monitoring

The primary concern in monitoring and tracking of women with normal results is compliance with regular screening guidelines. The responsibility for that effort should lie with the woman's health care provider, who interacts regularly with the woman and can inform her of the schedule appropriate for her. Ultimately, the responsibility for compliance with screening guidelines lies with the woman herself (Aalders and Schade, 1991).

OPTION: Women may be sent a reminder before their next appropriate screening date. (B)

For referred and self-requesting women, this reminder may be communicated by the referring health care provider rather than by the mammography facility, according to prearranged protocols. If a woman does not have a health care provider, the mammography facility is responsible for monitoring and tracking.

Both written reminders (personal letter or postcard) to the woman and facilitated scheduling during an office visit increase use of screening mammography (Chambers, Balaban, Carlson et al., 1989; Hurley, Jolley, Livingston et al., 1992; Nattinger, Panzer, and Janus, 1989; Wolosin, 1990). Computerized patient records that prompt physician compliance with screening recommendations also have a positive effect on patient referral to mammography (Harris, O'Malley, Fletcher et al., 1990; McDonald, Hui, Smith et al., 1984; McPhee, Bird, Fordham et al., 1991). Computerized patient records and computer-generated letters offer

efficiencies in many practice settings (Gann, Melville, and Luckman, 1993; Haug, Tocino, Clayton et al., 1987; Payton, 1991). Other approaches may be needed to increase the use of screening mammography by low-income and non-English-speaking patient populations (Coll, O'Connor, Crabtree et al., 1990; Lacey, Phillips, Ansell et al., 1989; Lane, Polednak, and Burg, 1992; Lovejoy, Jenkins, Wu et al., 1989; Stein and Fox, 1990; Vernon, Vogel, Halabi et al., 1992).

STRONG RECOMMENDATION: The primary responsibility for communicating a recommendation for short-interval followup, diagnostic mammography, or adjunctive diagnostic procedures rests with the referring health care provider or, for women without a provider, with the mammography facility. (B)

For women without a health care provider, the mammography facility that performed the initial mammography examination should be responsible for performing or arranging for the future examination or the immediate additional views and/or procedures to be performed. This should be followed by onsite consultation with the woman or prompt communication by mail to report the results and recommended next steps. The woman herself is responsible for complying with followup recommendations. However, it is important that she receive written results and recommendations in lay language using culturally relevant terms.

When the health care provider named by the woman does not accept the report, the mammography facility should treat the woman as if she does not have a provider and should assist her in identifying a provider who will accept her as a patient and to whom all reports should be sent. Important issues to the patient in identifying a provider are location, hours of operation, transportation, cost, and acceptance of insurance, Medicaid, or Medicare.

STRONG RECOMMENDATION: The referring health care provider is responsible for the followup, monitoring, and tracking of the woman whose result is abnormal and for whom a biopsy is recommended. The mammography facility should assist self-referred women in finding a health care provider who will assume followup responsibility. (B)

A recommendation that biopsy be considered introduces the involvement of other medical specialists and additional considerations that are best evaluated, discussed, and decided upon by the patient and her health care provider, with the interpreting physician providing consultative support. Decisions about referrals to appropriate medical personnel, such as a surgeon, should be made by the woman in consultation with her provider.

The mammography facility should maintain a tracking system to monitor patient compliance with recommendations for biopsy. Compliance may be monitored through direct communication with the woman's referring or designated health care provider.

The interpreting physician and other mammography facility personnel should continue to be available to the woman and her provider to discuss the interpretation of abnormal findings. Both the woman's provider and the mammography facility should implement tracking systems, which have been shown to improve patient compliance with followup recommendations (Aalders and Schade, 1991; Chambers, Balaban, Carlson et al., 1989; Elsenhans, 1991; Haug, Tocino, Clayton et al., 1987; Monticciolo and Sickles, 1990; Robertson and Kopans, 1989).

OPTION: The mammography facility may choose to schedule and track recommended followup breast imaging examinations. If so, the mammography facility should clearly communicate this arrangement to the referring health care provider and notify the referring health care provider if the woman does not comply with the followup recommendation. (C)

RECOMMENDATION: Recommended diagnostic mammography, including additional views and recommended adjunctive diagnostic procedures, should be performed by the mammography facility as soon as possible. If the mammography facility does not schedule these additional procedures directly with the woman, it should contact the woman's health care provider with information about the abnormal result and recommended followup. (C)

The performance of additional mammographic views is not considered a medical emergency. Nonetheless, additional views and adjunctive diagnostic procedures should be done as soon as possible—at least within 1 month.

Facilities that have only screening services provide an important and cost-efficient service to asymptomatic women, most of whom do not need additional diagnostic imaging. However, quality care is facilitated by immediate, onsite performance of additional studies made necessary by an abnormal screening mammogram. Assistance with scheduling necessary additional studies facilitates the highest compliance with followup of breast imaging recommendations (Cardenosa and Eklund, 1991; Monsees, Destouet, and Evens, 1988; Rubin, Frank, Stanley et al., 1990).

There are some reports that Medicare regulations (Department of Health and Human Services, 1990) may be interpreted to prevent immediate diagnostic followup of an abnormal screening mammogram, especially in cases where the woman is self-referred or self-requesting. However, this interpretation of Medicare regulations is not correct. Medicare covers immediate diagnostic followup of problems identified in a screening mammogram. The panel recommends that the Health Care Financing Administration regional or central offices be notified about any problems identified in this regard. Interpreting physicians should document that a finding present on the screening examination required additional imaging before a diagnosis could be made.

Mammography Report

STRONG RECOMMENDATION: The official mammography report should be arranged with a brief initial statement concerning the reason for the examination, followed by a description of the breast composition, a description of significant findings, a statement regarding comparison with prior examinations, and an impression that should include overall assessment and recommendations. The report should use standardized terminology. (B)

Breast composition may be described as (1) almost entirely fat; (2) there are scattered fibroglandular densities that could obscure a lesion on mammography; (3) breast tissue is heterogeneously dense, which may lower the sensitivity of mammography; (4) breast tissue is extremely dense, which lowers the sensitivity of mammography. An implant code should be added if an implant is present. Description of findings should use standardized terminology:

- Masses—describe:
  - Shape
  - Margin characteristics
  - Density
  - Location (clock face)
  - Size
- Calcification—describe:
  - Element morphology
  - Distribution
  - Location (clock face)
- Other—describe:
  - Architectural distortion
  - Asymmetry
  - Skin and/or nipple retraction
  - Skin and/or trabecular thickening

A concise and understandable report increases the use of screening and diagnostic mammography (Hindle, 1991). The American College of Radiology (ACR) has developed a Breast Imaging Reporting and Data System (BI-RADS™) containing standardized terminology and recommendations (Kopans, 1992a; Kopans and D'Orsi, 1992; Kopans, D'Orsi, Adler et al., 1993). Using this terminology, three experienced interpreting physicians produced almost identical receiver operator characteristics curves on 300 test cases (D'Orsi, Getty, Swets et al., 1992). Uniform terminology with a structured delivery should eliminate confusion in communicating results (D'Orsi and Kopans, 1993; Homer, 1984; Kopans, 1992a; Kopans and D'Orsi, 1992; Sierra, Bisesi, Rosenbaum et al., 1992).

STRONG RECOMMENDATION: Any clinical question raised by the referring health care provider should be addressed in the report. (B)

This represents good medical practice and is universally accepted. Clinical concerns usually relate to a palpable, focal, asymmetric mass or area in the breast, nipple discharge, focal persistent pain, and nipple or skin change. Radiopaque markers such as BBs placed on focal, palpable findings or areas of localized pain may enhance further patient management. Nipple discharge or skin and/or nipple change do not require markers, but a statement in the report indicating the presence (or absence) of mammography findings that support (or do not support) the clinical impression is helpful. Ductography may be helpful in identifying intraductal lesions. If no findings are present on the mammograms when clinical findings are evident, a statement should be added urging the clinician to address these areas of clinical concern independent of mammography results.

STRONG RECOMMENDATION: The mammography report should include an overall assessment of the findings and recommendations for further action, if warranted. (B)

The report should include one of the assessments and recommendations for future action listed below, as warranted:

- Needs Additional Evaluation (A)—This may take the form of additional mammographic views and/or ultrasonography or other procedure.
- Negative (N)—(Routine followup.) Nothing to comment on. If there is a clinical finding, a statement indicating that this finding should be dealt with independently of the negative mammogram should be added.
- Benign Finding (B)—(Routine followup.) Also negative, but the interpreting physician may wish to describe a typically benign finding: e.g., calcified fibroadenoma.
- Probably Benign Finding (P)—Short-interval followup suggested. A finding with a very high probability of being benign and not expected to change over the followup interval.
- Suspicious Finding (S)—Biopsy should be considered. A finding without the characteristic morphology of breast cancer but having a definite probability of being malignant.
- Highly Suggestive of Malignancy (M)—Appropriate action should be taken. These findings have a high probability of being cancer.

These assessments and recommendations are from the American College of Radiology's Breast Imaging Reporting and Data System, or BI-RADS™ (Kopans, D'Orsi, Adler et al., 1993). A classification system will aid in patient management, increase use of mammography, and instill confidence in both patient and clinician. The clear description of levels of confidence for the presence of malignancy, as outlined in the assessment scales, can aid understanding of the report, enhance effective assignment of

patients, and simplify long-term tracking (Kemp and Jackson, 1987; Rosenbaum, 1990; Schutte, 1985).

Results of second-opinion examinations should be treated the same as results of diagnostic examinations. A report should be sent to the health care provider and results passed on to the woman. If the results of the first report and second opinion are substantially different and will affect the woman's further care, this should also be communicated directly to the health care provider. If an oral second opinion is given to the referring health care provider, a brief note in a log documenting the interchange may be prudent. The note should include the name of the original facility, the determination, whether the impression is substantially different, and recommendations.

OPTION: A computer system is not required for implementation of any guideline recommendations. However, the use of a computer system is encouraged to facilitate data collection and tracking of women. (B)

For any system to be useful it must be reliable and easy to use (Baron and Strange, 1990; Robbins, Vincent, Shaffer et al., 1988). A coding system will ease production of computerized reports and greatly simplify quality assurance. It will also facilitate comparison of data among interpreting physicians and help highlight areas requiring further training (American College of Radiology, 1993a; Bramble, Chang, and Martin, 1989).

Recordkeeping

RECOMMENDATION: The interpreting physician should keep data on each patient that cover patient characteristics, mammography and other breast imaging, mammography interpretation and reporting of results, and other information such as whether a biopsy was recommended. (C)

This information can be collected before, during, and after the mammography examination. It should be kept in the form of a medical record for that patient. Information retention permits a better mammography audit, boosts confidence in accuracy of interpretation, increases the likelihood of compliance with recommendations for followup and/or subsequent management (Elsenhans, 1991; Monticciolo and Sickles, 1990; Sickles, 1990a and 1992), encourages women and physicians to follow guidelines for screening (Sickles, 1990b; Tocino, 1989), and encourages third-party payers to reimburse for screening mammography (Clark, King, and Worden, 1989; Haug, Tocino, Clayton et al., 1987; Laszlo, 1985).

The following data can be included:

- Patient-related data:
  - Demographic (age, race, ethnicity, sex).
  - Prior mammography (date, location).
  - Patient's personal history (cancer risk profile—history of prior breast cancer, date, treatment; history of prior breast surgery, date, outcome, hormonal status).
  - Family history relevant to breast cancer (first-degree relative; pre- or post-menopausal).
  - For a diagnostic study, pertinent clinical data (complaints, symptoms, clinical breast examination results).
- Mammography and other breast imaging data:
  - Whether a screening or diagnostic examination was performed.
  - Which technologist performed the mammogram.
  - Whether or not comparison was made with a prior study.
  - For a diagnostic study, what diagnostic views or imaging procedures were performed.
- Mammography interpretation and reporting data:
  - Film interpretation, report.
  - For a diagnostic study, what specific attention was paid to the area or breast for which abnormal clinical breast examination results were found by the referring health care provider.
  - Recommendation for further followup (if indicated).
  - Documentation of reporting (including the date the report was sent or communicated): written report or recommendation to the referring health care provider; written report, letter, or recommendation to the patient; any telephone communications.
- Other data:
  - Patient education offered or given.
  - Date for followup or next screening examination.
  - For biopsy, pathology report, surgical outcome, and staging information.

OPTION: Retaining information in a computerized format has been promoted in the recent literature, but other formats permitting ease of access and retrieval may also be acceptable. (C)